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MANDOL® I.M./I.V.
Cefamandole Nafate

Brief Summary.
Consult the package literature for prescribing information.

Indications and Usage: Mandol is indicated for the treatment of serious infections caused by susceptible strains of the designated microorganisms in the diseases listed below:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae, Klebsiella* species, *Staphylococcus aureus* (penicillinase and non-penicillinase-producing), beta-hemolytic streptococci, and *Proteus mirabilis*

Urinary tract infections caused by *Escherichia coli, Proteus* species (both indole-negative and indole-positive), *Enterobacter* species, *Klebsiella* species, group D streptococci (*Note:* Most enterococci, e.g., *S. faecalis*, are resistant), and *S. epidermidis*

Peritonitis caused by *E. coli* and *Enterobacter* species

Septicemia caused by *E. coli, S. aureus* (penicillinase and non-penicillinase-producing), *S. pneumoniae, S. pyogenes* (group A beta-hemolytic streptococci), *H. influenzae*, and *Klebsiella* species

Skin and skin-structure infections caused by *S. aureus* (penicillinase and non-penicillinase-producing), *S. pyogenes* (group A beta-hemolytic streptococci), *H. influenzae, E. coli, Enterobacter* species, and *P. mirabilis*

Bone and joint infections caused by *S. aureus* (penicillinase and non-penicillinase-producing)

Clinical microbiologic studies in nongonococcal pelvic inflammatory disease in females, lower respiratory infections, and skin infections frequently reveal the growth of susceptible strains of both aerobic and anaerobic organisms. Mandol has been used successfully in these infections in which several organisms have been isolated. Most strains of *Bacteroides fragilis* are resistant in vitro; however, infections caused by susceptible strains have been treated successfully.

Specimens for bacteriologic cultures should be obtained in order to isolate and identify causative organisms and to determine their susceptibilities to cefamandole. Therapy may be instituted before results of susceptibility studies are known; however, once these results become available, the antibiotic treatment should be adjusted accordingly.

In certain cases of confirmed or suspected gram-positive or gram-negative sepsis or in patients with other serious infections in which the causative organism has not been identified, Mandol may be used concomitantly with an aminoglycoside (*see* Precautions). The recommended doses of both antibiotics may be given, depending on the severity of the infection and the patient's condition. The renal function of the patient should be carefully monitored, especially if higher dosages of the antibiotics are to be administered.

Antibiotic therapy of beta-hemolytic streptococcal infections should continue for at least ten days.

Contraindication: Mandol is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: BEFORE THERAPY WITH MANDOL IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY, PARTICULARLY TO DRUGS. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE EPINEPHRINE AND OTHER EMERGENCY MEASURES.

In newborn infants, accumulation of other cephalosporin-class antibiotics (with resulting prolongation of drug half-life) has been reported.

Precautions: Although Mandol rarely produces alteration in kidney function, evaluation of renal status is recommended, especially in seriously ill patients receiving maximum doses.

Prolonged use of Mandol may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Nephrotoxicity has been reported following concomitant administration of aminoglycoside antibiotics and cephalosporins.

A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solution or with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly). There may be a false-positive test for proteinuria with acid and denaturization-precipitation tests.

As with other broad-spectrum antibiotics, hypoprothrombinemia, with or without bleeding, has been reported rarely, but it has been promptly reversed by administration of vitamin K. Such episodes usually have occurred in elderly, debilitated, or otherwise compromised patients with deficient stores of vitamin K. Treatment of such individuals with antibiotics possessing significant gram-negative and/or anaerobic activity is thought to alter the number and/or type of intestinal bacterial flora, with consequent reduction in synthesis of vitamin K. Prophylactic administration of vitamin K may be indicated in such patients, especially when intestinal sterilization and surgical procedures are performed.

In a few patients receiving Mandol, nausea, vomiting, and vasomotor instability with hypotension and peripheral vasodilatation occurred following the ingestion of ethanol.

Cefamandole inhibits the enzyme acetaldehyde dehydrogenase in laboratory animals. This causes accumulation of acetaldehyde when ethanol is administered concomitantly.

Usage in Pregnancy—Safety of this product for use during pregnancy has not been established.

Usage in Infancy—Mandol has been effectively used in this age group, but all laboratory parameters have not been extensively studied in infants between one and six months of age; safety of this product has not been established in prematures and infants under one month of age. Therefore, if Mandol is administered to infants, the physician should determine whether the potential benefits outweigh the possible risks involved.

Adverse Reactions: *Hypersensitivity*—Maculopapular rash, urticaria, eosinophilia, and drug fever have been reported. These reactions are more likely to occur in patients with a history of allergy, particularly to penicillin.

Blood—Thrombocytopenia has been reported rarely. Neutropenia has been reported, especially in long courses of treatment. Some individuals have developed positive direct Coombs tests during treatment with the cephalosporin antibiotics.

Liver—Transient rise in SGOT, SGPT, and alkaline phosphatase levels has been noted.

Kidney—Decreased creatinine clearance has been reported in patients with prior renal impairment. As with some other cephalosporins, transitory elevations of BUN have occasionally been observed with Mandol; their frequency increases in patients over 50 years of age. In some of these cases, there was also a mild increase in serum creatinine.

Local Reactions—Pain on intramuscular injection is infrequent. Thrombophlebitis occurs rarely. [01 1981]

Lilly

Additional information available to the profession on request.
Eli Lilly and Company
Indianapolis, Indiana 46285

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